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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/598,026 | 10/18/2007 | Alastair Edwin McAuley | FPHCR.112NP | 9347 |

20995 7590 03/04/2011
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| EXAMINER |
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CHU, KAIYEU K

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3771

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| NOTIFICATION DATE | DELIVERY MODE |
|-------------------|---------------|

03/04/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/598,026 | Applicant(s) MCAULEY ET AL. | |
| | Examiner KEVIN CHU | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-20, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/16/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the new application for patent filed on 8/16/2006. The response to restriction requirement filed on 1/12/2011 has been received and considered. In addition, the preliminary amendment filed on 8/16/2006 has been considered. This preliminary amendment canceled claim 21. As such, claims 1-20 and 22 are presently pending.

Election/Restrictions

2. Applicant's election **with** traverse of Invention I in the reply filed on 1/12/2011 is acknowledged. The traversal is based on the following grounds: In the second full paragraph on page 5 of the Remarks, Applicant argues that claims 18-20 and 22 belong in Group 1. Applicant states that Group 1 corresponds to at least claims 1-10, 18-20, and 22. In the last paragraph on page 5 of the Remarks, Applicant asserts that the claims should not be characterized as "product and process" claims. The Examiner finds applicant's arguments persuasive. However, after reconsideration, a species restriction will be required.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the species of Figs. 2-6 (corresponding to claims 11-12) and the species of Figs. 9-13 (corresponding to claims 2-10, 13-20, and 22). The species are independent or distinct because the species of Figs. 2-6 comprise a first

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special technical feature of a prong having an end that is *flared outwardly*. On the other hand, the species of Figs. 9-13 comprise a second special technical feature comprising *a flange and an end that becomes progressively thinner in cross-section towards its tip*. A fair glance at the embodiment illustrated in Figs. 9-13 of the Drawings will indicate that it lacks the feature of a prong having an end that is *flared outwardly*. Likewise, a fair glance at the embodiment illustrated in Figs. 2-6 of the Drawings will indicate that it lacks the feature of *a flange and an end that becomes progressively thinner in cross-section towards its tip*. In addition, these species are not obvious variants of each other based on the current record.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1.

4. REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

WHEN CLAIMS ARE DIRECTED TO MULTIPLE CATEGORIES OF INVENTIONS

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

5. **Applicant's election without traverse of claims 1-10, 18-20, and 22 in the reply filed on 1/12/2011 is acknowledged.** These claims correspond with the species of Figs. 9-13. The Examiner believes claims 13-17 also belong to this species because the features recited in those claims (e.g. two nasal prongs that are oval and shaped to follow the contours of human nares, angled toward one another, and comprise a step and a protrusion) read on the species of Figs. 9-13. Thus, claims 1-10, 13-20, and 22 are readable on the species of Figs. 9-13.

6. **Claims 11-12 are withdrawn from further consideration** pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 95 (in Fig. 17).
8. The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “40, 41” on line 31 of page 7 of the Specification (also on line 25 of page 11 of the Specification).
9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Abstract

10. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract

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on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "comprises," should be avoided. **In the present Abstract, the term "comprises" (in line 1 of the Abstract), should be avoided.** The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specification

11. The disclosure is objected to because of the following informalities:

- The descriptions of Fig. 14 and Fig. 16 on page 4 of the Specification seem to be switched. That is, the description of Fig. 14 (lines 20-21) appears to describe Fig. 16 as shown in the Drawings, and the description of Fig. 16 (lines 23-25) appears to describe Fig. 14 as shown in the Drawings.
- The term "apertures 48" in line 18 on page 8 of the Specification should be corrected to -apertures 46- in order to correct the presumed typographic error.
- The term "channels 85" in line 28 on page 10 of the Specification should be corrected to -channels 86- in order to correct the presumed typographic error.

Appropriate correction is required.

12. The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter because the limitation in claim 3 reciting "said head strap

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is a small flexible tube” (lines 1-2) lacks proper basis in the specification. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Appropriate correction is required.

Claim Objections

13. Claims 1, 10 and 20 are objected to because of the following informalities:

- The term “nasal cannula” in line 2 of claim 1 should be corrected to - -a nasal cannula- - in order to prevent any lack of antecedent basis problems.
- Examiner finds the term “thinner” in line 2 of claim 10 to be confusing because the Examiner is uncertain how a cross-section becomes thinner. Examiner believes that using a different term, such as “smaller,” would be more appropriate.
- The term “gases,” in line 3 of claim 20 should be corrected to - -gases.- - in order to correct the presumed typographic error.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. **Claims 1-10, 13-20 and 22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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16. Claim 1 recites the term "high flow delivery" in lines 8-9. However, it is uncertain as to what constitutes "high flow delivery."

17. Claim 1 recites the limitations "said humidified gases" in line 3 and "said patient's airway" in lines 9-10. There is insufficient antecedent basis for these limitations in the claim.

18. Claim 8 recites the limitation "the other side" in line 3. It is unclear as to what "the other side" refers to. The other side of the flange?

19. Claims 2-7, 9-10, 13-20, and 22 are rejected as being dependent on rejected claim 1.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. **Claims 1-2, 4-7, 9, and 22** are rejected under 35 U.S.C. 102(e) as being anticipated by Thomlinson et al. (2005/0011524 A1).

22. Regarding claim 1, Thomlinson teaches in Fig. 1 a breathing assistance apparatus comprising:

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- a nasal cannula (2), shaped to fit within a user's nares, and adapted to deliver humidified gases to said user,
- a pressurized source of gases (see [0199], lines 1-5),
- transportation means (36) adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,
- wherein said nasal cannula includes two prongs (10, 12) that are capable of high flow delivery (see [0198], lines 11-14) of said humidified gases and create a positive airway pressure in said patient's airway, said prongs having an angled end (as shown in Fig. 1, the prongs are angled towards one another; also, Fig. 2 shows that the tips of the prongs are angled on the edges), such that in use, gases flowing through said prong are directed to said users nasal passages.

23. Regarding claim 2, Thomlinson teaches that the nasal cannula includes arms (see element 28 in Fig. 8; see element 120 in Fig. 30) to attach a head strap (element 103 in Fig. 36) to said cannula (such as shown in Figs. 37 and 38).

24. Regarding claim 4, Fig. 1 of Thomlinson teaches that the prongs each include a flange (20) near its end (as shown in Fig. 1).

25. Regarding claim 5, Thomlinson teaches that the prongs are two nasal prongs (10, 12) that are angled toward one another (as shown in Fig. 1) so that they are capable of helping prevent dislodgment from said user's nares and assisting in flow of

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gases into the user's nasal passages, and the prongs are oval in shape (as shown in Fig. 4) such that they substantially follow the shape and contour of human nares.

26. Regarding claim 6, Thomlinson teaches that the flange causes the sealing of said prongs in the nares of the said user in use (see [0201], lines 5-8; see Abstract, lines 13-15).

27. Regarding claims 7 and 22, Thomlinson teaches that each flange is a thin flexible extension (see Abstract, lines 13-15; a deformable flange is a flexible flange) that extends substantially completely around the circumference of each prong (as shown in Fig. 4).

28. Regarding claim 9, Thomlinson teaches that each prong includes a flange (20), recessed area (area between 18 and 20, as shown in Fig. 1) and shaped end (portion of prong from 18 to 44), wherein the recessed area is disposed between said flange and said shaped end (as shown in Fig. 1) and in use said flange extends into and seals within a user's nares (see [0201], lines 5-8; see Abstract, lines 13-15).

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

31. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomlinson in view of Argraves (6,298,850 B1).

32. Regarding claim 3, Thomlinson teaches all of the previously claimed limitations but fails to further teach that the head strap is a small flexible tube. However, Figs. 1-2 of Argraves teach a nasal cannula assembly (10) with a head strap (40) that is a small flexible tube (see column 2, lines 40-49; see column 3, line 60 – column 4, line 8), which “solves the problem of user comfort and hair entanglement” (column 2, line 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the head strap of Thomlinson to be a small flexible tube, as taught by Argraves, to enhance patient comfort when donning the head strap.

33. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomlinson in view of Matula, JR. et al. (2005/0205096 A1).

34. Regarding claim 8, Thomlinson teaches all of the previously claimed limitations but fails to further teach that the flange is elliptical in shape with one side of the flange

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extending out from the prong further than the other side of the flange. However, Matula teaches a nasal breathing assistance apparatus (as shown in Fig. 1) comprising a nasal cannula (as shown in Fig. 9A and 9B) with prongs (64) and flanges (66) on the prongs, wherein each flange is elliptical in shape with one side of the flange extending out from the prong further than the other side of the flange (as shown in Fig. 9B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify each flange of Thomlinson to be elliptical in shape with one side of the flange extending out from the prong further than the other side of the flange, as taught by Matula, in order to increase comfort for some users when using the nasal cannula.

35. **Claims 10 and 13-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thomlinson in view of Ziaee (2002/0096178 A1).

36. Regarding claim 10, Thomlinson teaches all of the previously claimed limitations but fails to further teach that the shaped end becomes progressively thinner in cross-section towards its tip. However, Fig. 1 of Ziaee teaches a nasal mask with nasal pillows (24), wherein each nasal pillow consists of a prong (24), a flange (middle flap of nasal pillow 24), recessed area (area between the middle and top flaps of nasal pillow 24, as shown in Fig. 1) and shaped end (portion of nasal pillow 24 from the top flap to tip of nasal pillow 24), wherein the recessed area is disposed between said flange and said shaped end (as shown in Fig. 1), and wherein the shaped end becomes progressively smaller in cross-section towards its tip (as shown in Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to modify each prong of Thomlinson so that it has a shaped end that becomes progressively smaller in cross-section towards its tip, as taught by Ziaee, in order to increase comfort for some users when inserting the prongs up their nostrils.

37. Regarding claims 13-15, please refer to the rejection of claim 5 for reasoning.

38. Regarding claims 16 and 17, Thomlinson teaches that the prongs can each have a step formed in them (such as the step formed by the intersection between 44 and 18 as shown in Fig. 1; or such as the steps shown at nasal prongs 24 and 26 in Fig. 8) such that in use the sides of said prongs abut the user's nasal septum so as to prevent the prongs from dislodging from said user's nares, wherein each of the prongs include a protrusion (such as element 18 in Fig. 1; or such as the protrusions shown at nasal prongs 24 and 26 in Fig. 8) formed opposite said step that assists in correct orientation of the prongs within said user's nares.

39. Regarding claim 18, Thomlinson teaches that the nasal cannula includes a body (see elements 14 and 16 in Fig. 1) that has a plurality of apertures (see element 22 in Fig. 3; see [0277], line 1, [0278], lines 1-8, [0279], lines 1-3, and [0280], lines 1-7) that act as a bias flow outlet vent for gases exhaled by said user.

40. Regarding claim 19, Thomlinson teaches that the nasal cannula is connected to the transportation means by way of a ball and socket joint (see element 225 in Figs. 59-60; see [0317], lines 8-14).

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41. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Thomlinson in view of Ziaee as applied to claims 10 and 13-19 above, and further in view of Hill et al. (6,651,658 B1).

42. Regarding claim 3, the modified Thomlinson teaches all of the previously claimed limitations but fails to further teach a humidification means adapted to, in use, be in fluid communication with said source of gases and said transportation means and adapted to in use humidify said gases. However, Hill teaches a portable oxygen system (see Abstract) that includes a humidification means (148) "for adding moisture to the air flow in the system" (column 9, lines 9-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the breathing system of the modified Thomlinson with a humidification means, as taught by Hill, in order to add moisture to the delivered air to make it more comfortable for patients to breathe.

Conclusion

43. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gunaratnam et al. (2004/0226566 A1), Tohara (7,207,333 B2), Ziaee (2002/0053347 A1), Wilkie et al. (7,201,169 B2), Lovell et al. (7,210,481 B1), Wood (5,533,506), Gwaltney (5,595,174), Dickerman et al. (5,113,857), and Sleeper et al. (2005/0028822) teach nasal cannulas with prongs having angled ends and/or flanges. Izuchukwu (2003/0005933 A1) teaches a pressurized gas supply system comprising a hollow strap.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN CHU whose telephone number is (571)270-5376. The examiner can normally be reached on Monday-Friday 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KEVIN CHU/
Examiner, Art Unit 3771
2/23/2011

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771